EXHIBIT 22

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FRANCIS FENWICK, et al,
PLAINTIFFS

Vs.

CIVIL NO.
12-7354 (PGS)

RANBAXY PHARMACEUTICALS, INC.,
DEFENDANTS

MARCH 27, 2015
CLARKSON S. FISHER COURTHOUSE
402 EAST STATE STREET
TRENTON, NEW JERSEY 08608

B E F O R E: THE HONORABLE PETER G. SHERIDAN
U.S. DISTRICT COURT JUDGE
DISTRICT OF NEW JERSEY

COURT'S OPINION ON MOTION TO DISMISS AMENDED COMPLAINT

Certified as true and correct as required
by Title 28, U.S.C. Section 753
/S/ Francis J. Gable
FRANCIS J. GABLE, C.S.R., R.M.R.
OFFICIAL U.S. REPORTER

THE COURT: So, this is a motion to dismiss an amended complaint brought by Ranbaxy. There are five putative class members seeking a refund (Complaint 4B), or an exchange for replacement products of a prescription drug called atorvastatin (Complaint 4C). That drug reduces cholesterol and it is a generic of Lipitor. It is a pill taken daily, and will be referred to herein as the Ranbaxy pill.

Evidently, the Ranbaxy pills manufactured between September and November of 2012 contained a foreign substance (small glass particles)(Complaint at paragraph 34). The glass particles were about the size of a fine grain of sand (defendant's brief at page 9). In November 2012, the FDA found the Ranbaxy pills to be adulterated, and as a result Ranbaxy recalled certain lots of the Ranbaxy pills at the retail level. The retail level means that all Ranbaxy pills that were in the possession of pharmacies were recalled, but the ones consumers had purchased were not recalled or exchanged (Complaint at paragraph 2, paragraph 28 and paragraph 29).

In Count 1, plaintiffs allege that "defendants reasonably expected class members to ingest" the Ranbaxy pills which were below commercial standards and were unfit for buyers' ordinary purpose. As such, the Ranbaxy pills were not merchantable goods. Plaintiffs suffered an economic loss, and as such, the implied warranty of merchantability was breached

(NJSA 12A:2-214) (Complaint paragraphs 52-60).

Count 2 is similar to Count 1, except plaintiffs plead that the implied warranty of merchantability, as set forth in the UCC, was breached (paragraphs 61-71). Count 3 alleges defendants sold the Ranbaxy pills to plaintiffs through retailers, and defendants "provided an express warranty or guarantee concerning the quality, safety and integrity of its product." Defendants breached this express warranty and plaintiffs sustained damages (Complaint 72-79).

Count 4 is similar to Count 3, except Count 4 relies on the express warranty provisions set forth in the UCC (NJSA 12A:2-13). In addition, this count alleges the Ranbaxy pills were not of the promised quality and integrity (Complaint at paragraphs 80-88).

Lastly, in Count 5 plaintiffs allege defendants were unjustly enriched in that defendants "were unjustly enriched in the amount of money made by them through sale of the tainted product." (Complaint at paragraphs 91-93.)

Defendants argue that the complaint should be dismissed because the plaintiffs cannot enforce the Food and Drug and Cosmetic Act through a private cause of action, and alternatively, the New Jersey Products Liability Act subsumes any claim of plaintiffs. Defendants assert the plaintiffs are attempting to enforce the FDA's statute, since the complaint refers to the FDA actions and regulations. For example, the

complaint notes that the Ranbaxy pill was recalled, and was classified as a "Class II" recall. Class II is defined in the FDA regulations, and plaintiff refers to the Ranbaxy pills as adulterated, which is also a defined term within the FDA Act. Defendants argue their actions "were consistent with the FDA." That is, both the defendant and the FDA followed the FDA regulatory procedures manual. (Defendant's brief, page 11.)

The argument that the FDA actions control and such actions preclude any action for a refund or an exchange, makes little sense to me. When the FDA ordered the recall at the retail level, as opposed to the consumer level, it was confronted with the dilemma of whether it is safer for consumers to ingest the Ranbaxy pill and continue on their cholesterol reduction medications; or, whether it was safer to recall all Ranbaxy pills which had glass particles, and run the risk that the consumers may have adverse health effects due to the lack of the Ranbaxy pill. From this analysis, the FDA and defendant chose the former; but that in no way gives rise to defendant's conclusion that the FDA was indicating the pills were safe or the FDA was immunizing the defendant from all consumer remedies. The FDA balanced the risks of recalling all Ranbaxy pills against individual patient complications from ceasing the use of such Ranbaxy pills on a daily basis.

Defendant argues that each plaintiff "purchased the

product with the intent to use it for his or her personal use," and they ingested the product, but defendant argues that none of the plaintiffs allege that the product failed to deliver the promised amount of atorvastatin, or that the atorvastatin failed to deliver the promised pharmacological benefits. (Defendant's brief at page 12.) As such, none of the plaintiffs suffered damages.

To me, this is a tenuous argument, where defendants miss the point; that is, there are glass particles in the Ranbaxy pills, and plaintiffs object to ingesting same. Certainly the complaint articulates a very basic claim that plaintiffs purchased the Ranbaxy pills on the proposition that the generic was as safe as Lipitor, which is a condition that the Ranbaxy pills did not meet.

Generally, this is a contract dispute where principles of contract law are at issue. See, *Alloway v. General Marine*, 149 New Jersey 620 at 627 (1996). Within the plaintiffs' brief they primarily argue for a refund or replacement of the Ranbaxy pills. The brief states:

"The bottom line is that the plaintiffs purchased [Ranbaxy pills] and the pills were contaminated with glass particles. The plaintiffs did not get what they paid for. It should be obvious that the plaintiffs are entitled to a refund." (Plaintiff's brief at 1007.)

So, this claim is far different than the actions

undertaken by the FDA; and the plaintiffs are only seeking a basic contract remedy of a refund for pills that contain glass, a substance they did not bargain for when they purchased the Ranbaxy pills.

The defendant argues that the plaintiffs' case and damages are subsumed by the New Jersey Products Liability Act. The Court rejects that argument. First, the New Jersey Products Liability Act applies to such claims "brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." That's NJSA 2A:58C-1(b)(3). Here, the plaintiffs, in Count 3, specifically allege a breach of express warranty between the parties. And in Count 4 plaintiffs allege that the express warranty provision of the Uniform Commercial Code was also violated. (See NJSA 2A:58C-1(b)(3). As such, Counts 3 and 4 survive the defendant's subsumed theory, because they fit within the exception to that rule.

Moreover, the New Jersey Products Liability Act subsumes any product liability "claim brought by a claimant for harm caused by the product." The Products Liability Act defines harm as "A, physical damage to property other than to the product itself; B, personal physical illness, such as injury or death; C, pain and suffering, mental anguish or emotional harm; and D, any loss of consortium or service or

other loss deriving from any type of harm described in paragraphs A through C of this paragraph." (NJSA 2A:58C-1(b)(2)). The Third Circuit has noted that the Products Liability Act "effectively creates an exclusive statutory cause of action for claims falling within its purview." That's *Repola v. Morbark Industries*, 934 F.2d 483 at 492 (3d. Cir. 1991). Generally, if any of the plaintiff's claim constitute a Products Liability claim, they may be subsumed under the Products Liability Act. However, this case is not a Products Liability claim, the case does not come within the Products Liability Act because the complaint does not assert a claim for "harm" caused by a product. The plaintiff's claim is for a refund, and does not fall within any of the four sub-parts of the definition of harm that were outlined above. The claim is based on the fact that the plaintiffs did not receive what they paid for. They paid for a generic cholesterol lowering drug like Lipitor, but instead they received pills that contained glass particles, which are below commercial standards.

Turning to Count 5 of the complaint, in which unjust enrichment is alleged. Defendant argues that in order to support an unjust enrichment claim, plaintiffs must "allege a sufficiently direct relationship with the defendant to support a claim." (Defendant's brief at page 976.) Since the plaintiffs purchased the property from third-party retailers

rather than from the defendant manufacturer, the defendant argues that any claim by the plaintiffs here should be brought against the third-party retailers, because they are the entities with whom the plaintiffs have a contract. See, *Snyder v. Farnan*, 792 F.Supp.2d 712, 724 (D.N.J. 2011).

In short, Ranbaxy argues that the pharmacies (CVS or Express Script) should be the defendants. Here, the glass particles are the direct result of Ranbaxy's manufacturing process, and the relationship between the consumer and Ranbaxy is sufficiently direct in this case. As such, for the reasons set forth above, the motion to dismiss Count 5 is denied.

Defendant rely on *DeBenedetto v. Denny's*, 421 NJ Super 312 (AP 211 NJ Super LEXIS 63). In *DeBenedetto* plaintiffs sued Denny's because it deceptively presented a menu without disclosing the excessive amounts of sodium. In this case, we are primarily concerned with the manufacturing of pharmaceutical drugs. Quite frankly, I cannot see how a manufacturer and formulator of prescription drugs can be likened to the chef at Denny's. The facts are far different. So, the case before me is distinguishable from the *DeBenedetto* precedent.

The case of *Kury v. Abbott*, 212 Westlaw 124026, another case upon which Ranbaxy relies, is also distinguishable. In *Kury*, plaintiff avers mental anguish, physical pain and suffering, personal expenditure of time and

resources. All of these types of damages are different than what is being asserted here. Mental anguish and pain and suffering are more related to tort claims, and would be subsumed under the Products Liability Act. Here, the damages
00:26 are for a refund of the cost of the pills, which does not fit within the definition of harm, and in this case a tort remedy is not at issue.

At oral argument, the plaintiff brought up two other cases. One is *Hoffman v. Nutraceutical Corp.*, 2013 Westlaw
00:27 2650611. The defendant's argument was that the *Hoffman* case found that a vitamin, glucosamine chondroitin, contained some lead. And the *Hoffman* court found that although the defendant advertised or represented that the pill was pure, unadulterated and of the highest quality, the fact that there
00:28 were minor amounts of lead did not show that the vitamins were adulterated, and accordingly dismissed the claim.

The difference between this case and *Hoffman* is that the pills in fact contained glass, and the plaintiffs are simply seeking a refund. But in the *Hoffman* case, the
00:30 plaintiffs were seeking relief under the Consumer Fraud Act, and other common law causes, wherein they were seeking punitive damages. As a result, the analysis in the *Hoffman* is different and distinguishable from the case before this Court.

The defendants also cite to the *Lieberson v. Johnson*
00:31 *& Johnson* case, 865 F.Supp.2d 529. *Lieberson* is similar to

the *Hoffman* case, wherein plaintiff also is seeking a remedy under the Consumer Fraud Act, and is seeking punitive damages. Such a cause of action is not set forth in this case. It is a simple refund case, and as such, the cases are distinguishable.

So, in conclusion, based on the foregoing, the motion to dismiss the complaint is denied.